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Food-Drug-Cosmetic Law Journal

DECEMBER • 1957

Papers at FDA-FLI Informal Conference

GEORGE P. LARRICK . . . WINTON B. RANKIN
. . . ALBERT H. HOLLAND, JR., M. D. . . .
ROBERT S. ROE . . . ARTHUR A. CHECCHI

The Labeling of Dangerous Household Chemicals . . . . . .

C. JOSEPH STETLER and BERNARD E. CONLEY

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A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. On this basis, contributions and comments are invited.

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REPORTS

TO THE READER

About the Authors

The first portion of this December JOURNAL is devoted to a group of papers which were delivered at an FDA-FLI informal conference which was held in Washington, D. C., on November 26 (see "Meeting of Food and Drug Men," directly below). Among the conference speakers—all associated with the Food and Drug Administration, United States Department of Health, Education, and Welfare—were the following: **George P. Larrick,** Commissioner of Food and Drugs; **Winton B. Rankin,** assistant to the Commissioner; **Albert H. Holland, Jr., M. D.,** Director of the Bureau of Medicine, FDA; **Robert S. Roe,** Director of the Bureau of Biological and Physical Sciences, FDA; and **Arthur A. Checchi,** assistant to the Deputy Commissioner of Food and Drugs.

Also in this issue is an article, "The Labeling of Dangerous Household Chemicals," contributed by **C. Joseph Stetler,** director of the law department of the American Medical Association, and **Bernard E. Conley.** Dr. Conley is secretary of AMA's committee on toxicology.

John J. Galbally, who discuses the question of drug substitution as "gross immorality," serves as staff attorney with Smith Kline & French Laboratories.

Author of the continuing feature "Christopher Comments" is **Thomas W. Christopher,** associate dean and professor of law at Emory University, Georgia. Mr. Christopher, who is a member of the Georgia and the Alabama bars, was formerly a member of the Tuscaloosa, Alabama law firm of Phifer & Christopher.

"The Scientists' Forum," edited by Bernard L. Oser, presents a discussion on "The Significance of Potentiation to the Safety of Food Additives," by **John P. Frawley,** who will be remembered by our readers as a participant in the important symposium on "Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics," published in the October, 1955 JOURNAL. Dr. Frawley, who is now toxicologist for the Hercules Powder Company, was assistant chief of the Chronic Toxicity Branch of FDA. He is secretary of the toxicology subcommittee of the National Agricultural Chemicals Association.

Meeting of Food and Drug Men

The FDA-FLI informal conference which was held on November 26 in Room 5051 of the United States Department of Health, Education, and Welfare Building in Washington, D. C., had as its purpose the development of a closer relationship and a better understanding between the food industry and the Food and Drug Administration in its food administration of the Federal Food, Drug, and Cosmetic Act. The educational conference, which began at

10 a. m., continued past the middle of the afternoon.

The program included the following:

(1) A statement by Commissioner of Food and Drugs George P. Larrick, followed by introduction of the conferees.

(2) An official explanation of FDA's philosophy and organization, and of its operation, plans and needs for food administration of the Act. This portion of the program was open to discussion by the industry conferees.

(3) An official motion picture showing FDA's field work, also open to similar discussion.

(4) An FDA panel discussion of questions by the industry conferees.

Among representatives of food manufacturers were the following:

Charles L. Flounders, Abbotts Dairies; Joseph M. Creed, American Bakers Association; Dr. Roger H. Lueck and Robert J. Wardell, American Can Company; Dr. Richard A. Reinecke and Gilbert S. McInerny, American Home Foods, Inc.; R. D. Seely and Leon W. Goff, Anheuser-Busch, Inc.; Edward J. Smith, Beatrice Foods Company; John A. Grammer, Beech-Nut Life Savers, Inc.; A. M. Gilbert, The Best Foods, Inc.; Willis H. Gurley and A. C. MacMahon, The Borden Company; Charles D. Trombold and George J. Kuehnl, Campbell Soup Company; J. L. Murphy, Jr., M. W. McCaffrey and F. A. Nerrett, Canada Dry Ginger Ale, Inc.

E. S. Hartwick and Robert Kummel, Carnation Company; Robert L. Weinberg, Coastal Foods Company; E. J. Forio, John D. Goodloe and Julius G. Zimmerman, The Coca-Cola Company; George Faunce, Jr., Continental Baking Company; George H. Muth, Continental Can Company; Floyd J. Hosking and Michael F. Markel, Corn Industries Research Foundation; W. T. Brady and Samuel A. McCain, Corn Products Refining Company; Charles M. Fistere, Dairy Industry Committee; Charles Wesley Dunn and Frank T. Dierson, The Food Law Institute; Dr. Bernard L. Oser, Food and Drug Research Laboratories; T. A. Mulligan and Wilmer G. Williams, General Baking Company; Roy H. Walters and George S. Herr, General Foods Corporation; G. Cullen Thomas, General Mills, Inc.; Dan Gerber and William L. McKinley, Gerber Products Company.

Paul S. Willis, Grocery Manufacturers of America, Inc.; Frank Armour, Jr., C. L. Rumberger and P. M. Duff, H. J. Heinz Company; W. D. Van Doren, Hoffmann-LaRoche, Inc.; L. Ratzesberger, Jr., Illinois Canning Company; Eugene Brockenbrough, Institute of Shortening & Edible Oils, Inc.; E. L. Harding, Kellogg Company; C. W. Kaufman and Erwin P. Snyder, Kraft Foods Company; Robert M. Schaffner and Robert F. Finke, Libby, McNeill & Libby; Harold L. Suttle and W. E. Fairbanks, Thomas J. Lipton, Inc.; Richard L. Hall, McCormick & Company; Dr. Warren M. Cox, Jr., Mead Johnson & Company; Herman Fakler, Millers' National Federation.

Herbert R. Stratford and Lloyd M. McBride, Morton Salt Company; Edward A. Otocka and William E. MacKay, National Biscuit Company; Carlos Campbell and J. Harry Covington, National Canners Association; J. Huber Wetenhall and Robert S. Gordon, National Dairy Products Corporation; Edward O. Curran, The Nestle Company; Kent Upham and Leonard H. Farmer, Jr., Owens-Illinois Glass Company; William O. Dillingham and John T. Rice, Pabst Brewing Company; Richard S. Jones and Eunice Cox, Pet Milk Company; Philip F. Sherman, Pillsbury Mills, Inc.; William G. Werner and Edward W. Merkel, The Procter & Gamble Company.

Dr. F. N. Peters and Merrill E. Olsen, The Quaker Oats Company; Geoffrey Baker and F. A. Judell, Ralston Purina Company; John T. Tabor, The Seven-Up Company; Lincoln Lewis, Stokely-Van Camp, Inc.; Dr. L. W. Hazleton, Sunkist Growers; A. W. DeBirny, Sunshine Biscuits, Inc.; William N. Strack, Swift & Company; George Poland, United Fruit Company.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report Issued November 27, 1957.—One hundred and twenty-one voluntary actions to comply with the federal food and drug law were reported by Food and Drug Administration inspectors during the month of October, the agency announced on November 27. Manufacturers and warehousemen voluntarily disposed of 266 tons of unfit foods. The Administration reported that numerous plant improvements continue to be made by industry management to correct conditions pointed out by inspectors.

Reported in October, for example, was the remodeling of a grain elevator to eliminate traps where grain residues could collect, and to install complete new screening and dust-control equipment. The Administration noted that many other elevator operators have been spending substantial sums to improve the sanitary storage and handling of grain for human consumption.

Other food plant improvements reported in October included new additions and equipment in two apple cider and vinegar establishments. The improvements cost $40,000 and $20,000, respectively. Another vinegar manufacturer dumped a thousand bushels of apples and a flavor manufacturer dumped 36,000 pounds of frozen cherries because of spoilage. A sauerkraut manufacturer installed plastic tank covers and resurfaced its wooden kraut tanks. A brewer, who spent $20,000 on new bins, reported that he expects to save $700 per month in fumigation costs.

During the same month, 561 tons of contaminated foods were seized in 96 federal court actions. Ten seizures were made of substandard and misbranded foods and eight of substandard drugs and devices. Six drugs were seized on charges that they were misbranded with false and misleading curative claims, and two because they had been shipped without new-drug clearance.

Other seizures, involving inadequate warnings, dealt with a potent drug without a prescription label and also four shipments of a bowl cleaner without the poison labeling required by the Caustic Poison Act.

Informal Statements of General Policy or Interpretation.—A new advisory information service on the Federal Food, Drug, and Cosmetic Act and related laws was announced on November 30 by the Food and Drug Administration. The new service will provide statements on subjects of trade interest selected principally from letters written by FDA officials in response to inquiries from the food, drug and cosmetic industries.

Roundups of these statements will be published from time to time in the *Federal Register* under the title of "Informal Statements of General Policy or Interpretation." Persons on FDA's request mailing lists for *Federal Register* statements on foods, drugs or cosmetics will automatically receive reprints.

The Administration announced that the new service will serve somewhat the same purpose as the former "T. C." (Trade Correspondence) information series, which was discontinued early in 1946. This service served as a guide to uniform interpretation of the law by the FDA staff after passage of the present Food, Drug, and Cosmetic Act in 1938, and was later made available to others interested. When the Administrative Procedure Act of 1946 went into effect, the opinions of the FDA staff were formalized and published in the *Federal Register* as "Statements of General Policy or Interpretation." Publication of informal comments was discontinued.

The Administration has recognized that the formal statements of policy did not entirely take the place of the "T. C.'s." The informal series now provided will fill a need for technical information expressed by reporters, attorneys, trade associations, and members of regulated industries. It also complies with a recommendation in a 1955 report of the Citizens Advisory Committee on the Food and Drug Administration that a service similar to the "T. C.'s" be restored, the agency announced.

In the Public Health Service

Asian Influenza Incidence Drops.—Dr. Leroy E. Burney, Surgeon General of the Public Health Service, Department of Health, Education, and Welfare, announced on December 12 that the Nation seems to be emerging from the most widespread influenza epidemic in 40 years.

Estimates of new cases of Asian influenza, based on reports from the states, dropped to 225,000 for the last week of November. Since September 1, a total of between 15 and 20 million cases of Asian influenza had been estimated to have occurred in the United States. Outbreaks have been specifically reported by more than 50 per cent of the counties in the Nation.

"While the present epidemic wave appears at this time to be on the wane, further outbreaks are possible," Dr. Burney warned. "The disease can be expected to occur throughout January, February and March when influenza is usually at its peak. We can expect, moreover, that influenza occurring this season will be largely of the Asian strain.

"It is impossible to predict at this time whether or not the spread of the disease will mount again to epidemic proportions," the Surgeon General continued. "We do know, however, that Japan appears to be experiencing a second wave, an institution in California which had an epidemic in August had a small second outbreak this month, three counties in Arizona have recently had a second increase in influenza-like cases, and Louisiana reported a number of new school outbreaks in late October. No increase has been noted in the virulence of the disease.

"In view of these facts, the Public Health Service continues to urge vaccination, and to point out that this protection is particularly important to the chronically ill, the aged, and pregnant women."

Approximately 54 million cubic centimeters (doses) of Asian influenza vaccine had been released for civilian and military use up to the date of Dr. Burney's announcement.

"The rapid production and distribution of the vaccine over the past two months has unquestionably reduced the impact of the epidemic," Dr. Burney said.

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Papers at FDA–FLI Informal Conference

By GEORGE P. LARRICK, WINTON B. RANKIN, ALBERT H. HOLLAND, JR., M. D., ROBERT S. ROE and ARTHUR A. CHECCHI

This Symposium—of Food and Drug Administration Men—Was Held November 26 at the United States Department of Health, Education, and Welfare, Washington, D. C. Its Purpose Was to Develop Closer Relations and Understanding Between Food Industry and FDA

WELCOME

by

George P. Larrick

It is a pleasure to welcome so many of our old friends to this meeting and to greet the newcomers who have not previously had an opportunity to get a close look at the activities of the Food and Drug Administration.

This meeting was conceived as a get-acquainted meeting. Several months ago I mentioned to Charles Wesley Dunn that we have not had the same close communications with some of the leaders of the food industry that we have had, for example, in the drug industry. One has only to drop such a remark in the presence of Mr. Dunn and

Mr. Larrick, Who Is Commissioner of Food and Drugs, Has Held That Position Since 1954

he goes into action. Here and now I want to express my appreciation to The Food Law Institute and to Mr. Dunn for arranging this meeting.

This is a new experience for us as well as for you. We are going to try to give you a good look at our basic activities, practices and policies.

We have 16 district laboratories in principal cities; next year, there will be 17, through the addition of a new office in Detroit. Most of our research work continues to be located in the South Building of the United States Department of Agriculture.

We have scientists who are skilled in analyzing foods, drugs and cosmetics, and we have skilled inspectors to visit factories. Together, these men collect the evidence which will show whether or not a firm's practices meet the pure-food-law requirements. So, you see, the Food and Drug Administration is both a scientific, fact-finding institution and a law-enforcement organization. I may be prejudiced, but I believe it is the leading organization of its kind in the world.

To have the right perspective about our operations, one should know something about the relative size of the job at hand and the manpower we have to do it. Our principal duty is to see that food, drugs and cosmetics that move from one state to another are pure, wholesome and properly labeled. As you know, the basic statute authorizing the work is the Federal Food, Drug, and Cosmetic Act, better known as the pure food and drug law. Products subject to this law now represent an annual retail business volume of between $60 billion and $70 billion, not including goods which are produced and sold wholly within individual states. About one fourth of the income of the average American family is spent for these products. Thus,

our Administration protects every citizen of the country. We protect the manufacturer when he buys ingredients and products, and the distributor when he offers these for sale.

To administer this law, we now have about 300 inspectors; about 400 scientific workers, in both analytical and research activities; and a total staff of about 1,200. This is a very small organization when you consider the enormous scope of its responsibilities. Several years ago, it was estimated that we were inspecting food and drug plants at the rate of about once every eight or nine years. This was not a new situation. We have been a small outfit trying to do a big job. This has inevitably had its effects on our thinking, on our planning and on our policies. For example, it has for years compelled us to neglect certain areas of our work in order to give more attention to those problems which involve sanitation and public health.

All of this is relevant to a point which I particularly want to make.

The confidence which the American public has shown in its food and drug supply is one of the reasons we find ourselves in our present situation. Until recently, people have been taking the wholesomeness and safety of foods and drugs very much for granted. This is due both to the general high quality of your products and to the fact that they know there is a law, as well as an organization in Washington which is protecting them. Most people are not aware of the fact that we are spread so thin. Without the cooperation of food and drug manufacturers who want to comply with the law in every respect, our job would be impossible and the risk to public safety would be much greater.

More than ever before, manufacturers are acting voluntarily to bring about improvements in physical equipment or operating procedure as a result of recommendations made by our inspectors during factory inspections. The firms often notify us later that the changes have improved over-all operations.

We would like to see maximum compliance with the law with a minimum of court actions. It is much more economical—and better protection for the consumer—to *prevent* violations of the law than to prosecute after they have occurred.

"Preventive enforcement" requires channels of communication. One of the most important policies of the Food and Drug Administration is what we call the "open door" policy. The gist of it is that we are ready at any time to talk about law-observance problems with any

individual or group (unless there is active litigation that would require us to refer the subject to the attorneys).

Implicit in this open-door policy is the right to privacy of discussions. We believe that one of our most solemn obligations is to treat as confidential any inquiries we receive or meetings we have with people who come asking our advice regarding problems that affect their business and their observance of the law. But if, as a result of some individual inquiry, we reach some policy decision which is of general interest to some particular industry or to consumers, we can make that public, or if there is a need for some statement to be made about the deliberations of some conference or the conclusions reached, we may agree with the group regarding the kind of statement that will be given out. For the most part, however, there is never any publicity in regard to the private, informal discussions which we hold with industry members.

In addition to these informal contacts, we have formal working relationships with many organizations and groups in the food and drug industries and in the scientific professions. It would be impossible to estimate the good which has been accomplished through these contacts.

We welcome this opportunity of getting together to improve our understanding of one another's problems. We have arranged a program with emphasis on food and on the work done in Washington. However, you will see a short film also on the work of one of our 16 districts. Also, we have included a report on our drug activities, with special reference to a problem concerning food.

Without further delay, I would now like to turn the meeting over to members of the staff who will report on current phases of our work.

[The End]

ADULTERATIONS

by

Winton B. Rankin

No discussion of the work of the Food and Drug Administration would be complete without some mention of the extensive work we do on food adulterations.

The types we will consider are (1) those that cheapen, (2) those that occur because of toxic chemicals and (3) those that result from decomposition, insanitation and filth.

One of the most persistent problems we have is the cheapening of food. Some firms still deliberately add excessive amounts of water to their products. Some put ground cocoa shells in cocoa, cottonseed oil in olive oil, and other cheap ingredients in place of expensive ones.

If the cheapening is flagrant, it is not difficult to control, once the facts are known. The courts are not patient with people who sell horsemeat for beef or margarine for butter.

As the cheapening becomes more subtle, it is harder to stop. It is harder because the standard with which to compare the cheap product frequently is not so well recognized and because the manufacturer frequently maintains that the cheapened product is not the food we think is adulterated but is an entirely different one with an identity of its own that is legal under the descriptive labeling used.

However, when a manufacturer can reduce the cost of his article only a few per cent by eliminating, partially eliminating, substituting for or simulating an expected valuable ingredient, he may be able to secure sufficient price advantage to capture a material portion of the market. The practice is a continuing imposition on consumers and is quite hurtful to the better elements of industry as well.

We propose continued and expanded efforts to deal with this type of adulteration, but there are some practical problems that merit our joint attention:

How do we detect sophistication of food? Is the government obligated to do all of the developmental work? Will the better elements of industry let us know of sharp practices as they occur? Will the industries furnish us analytical techniques they have developed to detect the practices? Will the industries help us establish the composition that a food should have, particularly one for which there is not a definition of identity?

Some industries already furnish much assistance on these matters. We hope they will continue to do so, and that others will find it possible to let us have their help, too.

Toxic chemicals in food present another problem. In today's society we have to have chemicals in food that are not present when

it is grown. Their use may be justified to make the food keep longer, improve its quality, permit the manufacture of convenience foods that the housewife demands, and yield a host of other well-known benefits.

However, most chemicals are toxic at some level of feeding. Vitamin D and potassium iodide can cause trouble when we get too much. Yet each of these is quite useful in proper concentration. If we agree that we must have added chemicals in food, the question is how to regulate their addition to avoid hazard.

The present law does not offer a good solution. It says that any added chemical that is poisonous or deleterious shall be present in food only if:

(1) It is required in production or is unavoidable in good manufacturing practice.

(2) It then is present in an amount that the Secretary of Health, Education, and Welfare has determined by regulation to be safe.

Pesticides and coal-tar colors are exceptions.

This has been referred to as the "per se" doctrine of control. It holds that any poisonous or deletrious chemical not normally present in food shall be considered per se an adulterant unless it is necessary.

This doctrine is not compatible with modern food technology. Literally enforced, it would rule out of food many very useful substances. It would have been difficult when Vitamin D was first proposed for addition to milk to prove that it is necessary to get our Vitamin D that way; it would also have been difficult to establish the necessity of incorporating additional iodine in the diet through use of iodized salt. Responsible scientific groups in this country and abroad after careful study have concluded that chemical food additives should be tolerated in safe amounts when they accomplish a purpose useful to the consumer. In line with these considered views of the world's outstanding food scientists, we have endorsed a proposed change in the present law which would permit safe quantities of chemicals in food on a showing of usefulness (or functional value) in lieu of the showing of necessity presently required.

It is not our purpose here to debate the pros and cons of the two or three points where industry and government have not yet reached complete agreement on this proposed legislation. We mention it solely to give a well-rounded picture of the developments in this field.

Until such time as we have a more workable statute, there are a number of pressing matters that will not be completely solved. Numerous chemicals are in use which are toxic in high concentration but safe as used. They are being used without the formal tolerances which the present law requires.

Public Worry Concerning Safety of Food

There is a great deal of public concern today about the safety of our food supply. Much of it is unwarranted. But there is basis for considerable worry, and it will remain so until we have an adequate legislative solution.

Coal-tar colors are required to be "harmless" before they may be placed on the list of colors suitable for certification for use in food. Some of the colors previously considered harmless are now known to have an adverse effect on test animals in high dosage and we are having to remove them from the approved list. Proposed legislation embodying a new approach has been drafted by representatives of the color manufacturers and introduced in the Eighty-fifth Congress. Our department has not taken a position on the legislation as yet so we are not ready to comment on it.

Most chemicals used in the production of food on the farm are adequately controlled today. Chemicals to kill insects and other pests are handled under the Pesticide Chemicals Amendment, new drugs are handled under the law's new-drug section, and antibiotic-containing veterinary drugs are handled under the antibiotic section of the law.

The modern food-sanitation program of the Food and Drug Administration dates from 1938, when for the first time we got authority to deal directly with sanitary practices in the food factories. We gave first attention to those industries and firms which appeared to have the most significant sanitation problems. As sanitary conditions improved in plants producing finished products, we turned our attention to producers of raw materials.

Sanitation was judged in the factory largely by visual evaluation of the physical cleanliness of the plant. We concentrated on sources of gross contamination, such as rodents and insects which frequently are closely associated with the food supply. In the laboratory we developed a series of microscopic-analytical techniques to separate,

identify and measure foreign particles contributed to food by insanitary production conditions and by unfit raw materials.

Sanitation a Way of Life in Food Plants

Under these programs, marked improvements have been made in plant sanitation. While the initial impetus probably resulted from Food and Drug Administration work, the food industries have contributed in large measure to the present cleanliness of the American food supply. They are increasingly carrying the program forward on their own initiative. In general, they have adopted sanitation as a way of life. However, there is still considerable contamination of food with filth.

Additionally, there is a need that has not been met satisfactorily by the general sanitation program—the need to keep harmful bacteria out of foods. During the past generation, illnesses from contaminated milk and water have been almost eliminated in the United States. But we still have a steady incidence of bacterial upsets from food other than milk. The difficulty often results from poor handling where the food is prepared for serving. But there are circumstances that dictate closer attention in the factories themselves. These are: (1) high bacterial loads in some foods moving out of factories today; (2) an increasing production of convenience foods that are subject to bacterial inoculation during processing, are good media for bacterial growth, do not receive a final heat treatment in the plant that will destroy bacteria and are frequently eaten by the consumer without much, if any, heating.

We believe the time is here for the Food and Drug Administration and industry to take another look at food-plant sanitation. Several groups are considering the possibility of adopting standards of cleanliness which would rule a food fit or unfit according to its bacterial content. Against this approach is the alternative procedure of determining what manufacturing conditions contribute to microbial contamination and, by refining our methods of evaluating plant sanitation, correcting these conditions through the conventional procedure of plant inspection. Perhaps a combination of the two approaches will be necessary.

We believe the food industry can make major contributions by directing the attention of its sanitarians and technologists to this question. **[The End]**

DRUG ACTIVITIES

by
Albert H. Holland, Jr., M. D.

This is a welcome opportunity for me to speak with you about the safe use of drugs and the ways in which the Federal Food, Drug, and Cosmetic Act aids in achieving this goal. Our work is roughly divided into two main categories—(1) new drugs and (2) drugs and devices, or so-called enforcement activities. Taken together, they provide a degree of protection for you as an individual that otherwise is unobtainable. A priori, if a drug is not available to your physician, it is equally unavailable to you. You are both consumers—one professionally, the other actually. This legislation—the Federal Food, Drug, and Cosmetic Act—is a consumer-protection statute.

In essence, the law provides that, before a manufacturer can introduce a new drug into interstate commerce, he must first submit his data in the form of a new-drug application to the Food and Drug Administration for review. If the new-drug branch of the Bureau of Medicine concludes that the drug is safe, the application is made effective and the manufacturer can proceed to market it.

The new-drug branch is primarily concerned with the safety of the drugs which are the subject of new-drug applications. This means the drug is safe to use as directed for the indications proposed. Even safety itself is a relative—not an absolute—concept, nor does every therapeutic misadventure reflect on the safety of the drug. Rather, one must assess many factors in reaching a conclusion of safety, or lack of it. For example, the physician is willing to incur much greater risks in the presence of serious or life-threatening disease than he is with a relatively benign self-limited condition. It is the manufacturer's responsibility to market good drugs properly, but it is the physician's responsibility to use them properly and intelligently. Fundamentally,

the Federal Food, Drug, and Cosmetic Act is concerned with the medicine business—from manufacturer to consumer. It is not, however, concerned with the business of medicine as practiced by the physician; that is a matter for legal control by the individual states and professional control by local and national associations and professional societies.

The aspect of nutrition which has aroused the greatest interest in recent months is the possible role of dietary lipids in the etiology of arteriosclerosis, or hardening of the arteries, and heart disease. Obviously, the question arises whether by proper manipulation of diets we may be able to lower the incidence of coronary artery disease. Exciting as this prospect may be, it is well to bear in mind the fact that the available data are still fragmentary and, in many instances, conflicting.

There is now considerable evidence that various highly artificial dietary schedules can successfully alter serum cholesterol levels in the blood. It is well established that certain common fats of animal origin have a specific cholesterol-raising effect. This effect can be counteracted by eliminating most of the fat from the diet or by substituting large quantities of certain polyunsaturated fatty acids. Since the evidence to date is conflicting, it must be considered as unproven that the addition of these unsaturated fatty acids to diets already low or moderate in fat will have a comparable cholesterol-lowering effect. Furthermore, it is by no means clear whether such activity as these fatty acids possess is due to the degree of unsaturation, to the length of the fatty acid chain or to some as yet unidentified factor. There is certainly no proven correlation between this property and their biologic activity in preventing "essential fatty acid" deficiency states in animals.

Perhaps more important is the fact that the exact relationship between serum cholesterol levels and incidence of coronary artery disease remains unproven despite the rather voluminous medical literature on the subject. Is the elevated cholesterol level in a patient with coronary artery disease *cause* or *effect*? If *cause*, is the total cholesterol the important factor or some specific lipoprotein fraction? If one lowers cholesterol levels, may one not be doing some as yet undiscovered damage of another type? There is some animal evidence that prolonged diets high in polyunsaturated acids may precipitate deficiency of certain fat-soluble vitamins. Will this occur in man?

Will we adversely affect the levels of the hormones derived from cholesterol? More work is urgently needed to answer these various questions and to unravel the interrelated problems of the roles of exercise and of carbohydrates, proteins and total caloric intake.

At the present time, we in the Food and Drug Administration are maintaining open minds on the subject. Pending more conclusive studies, we feel that products containing polyunsaturated fatty acids should be labeled merely as simple dietary supplements. We have not, however, adversely criticized literature to physicians which suggests the substitution of these products for other fats in high-risk arteriosclerotic patients under medical supervision. On the other hand, we have taken exception to the representation of these fatty acids as "essential" or to any representations to the general public that they have either therapeutic or prophylactic value.

We agree with the conclusions of Page and his co-workers on the Nutrition Committee of the American Heart Association that "the evidence at present does not convey any specific implications for drastic dietary changes, specifically in the quantity or type of fat in the diet of the general population on the premise that such changes will definitely lessen the incidence of coronary or cerebral artery disease." Let us not forget that with present dietary habits we have attained the greatest average life expectancy yet achieved in the history of the world. The burden of proof must rest with those who wish to change these habits.

Much has been said about the problem of carcinogenicity resultant from chronic ingestion of a host of substances. As this has become a major pharmacological problem in the chemical, pesticide and food fields, so I believe it will increase in importance in the medical field as we advance in our quest to subdue or conquer chronic disease.

The subject poses some of our most difficult problems. Clear thinking is needed on the part of all of us. For example, if a substance is carcinogenic at any dose level, should it be permitted in the Nation's food supply? Assume that substance X is carcinogenic in a rat's diet at 1,000 parts per million, but does not appear to produce neoplasia at levels of 100 parts per million and less. Would you sanction its routine use in, say, bread or frozen foods? If so, at what maximum level? In just one foodstuff, or in several where the total cumulative dose may be significantly higher? The rats did not sustain lesions

at 100 parts per million. What about the cancer-susceptible individual? What about the patient with hepatic disease daily consuming this agent which is metabolized in the liver? Can it or will it be handled in the same way as by the normal liver? Might the rate of metabolism be sufficiently impaired so that a carcinogenic blood level would ensue? Again, what about synergistic, or even additive, effects with carcinogens from other sources? These are but some of the plaguing questions which remain largely unanswered. To market or not? In large part, the answers must come from medicinal chemistry and pharmacology.

One can argue that we permit the marketing of drugs capable of producing even greater injury—death at some doses. In small amounts, however, with no observed adverse effects they are exceedingly useful agents—even lifesaving. The potential carcinogens produce no observed adverse effects at appropriate dose levels and most are very useful. Is the analogy valid? Is it sound? Where are the facts from science? Is our biological data complete? Do we know enough about all of the biochemical and enzyme systems of the body in health and disease to permit us to predict with certainty? It is at this negotiating table that science, morality and progress must face reality and achieve workable solutions for the future. **[The End]**

FOOD RESEARCH

by

Robert S. Roe

Ever since the enactment of the first Federal Food and Drugs Act in 1906, a great deal of scientific research has been required to develop methods of analysis and the scientific facts needed to enable proper administration of the law.

More than ever before, an adequate scientific staff is essential to enable proper administration of the present Federal Food, Drug, and Cosmetic Act. The technological and scientific advances of the past several decades have had their applications to foods and drugs. This is reflected in new packaging, new processing, new forms of preservation, improved storage and distribution facilities, new products such as the many "convenience" foods, new potent "miracle" drugs and new chemicals that may find their way into foods either inadvertently or intentionally to serve some real or fancied purpose.

We are endeavoring to maintain an adequate staff of competent, well-trained scientists and to provide them with proper equipment and suitable facilities. This is fraught with many difficulties. There are problems in getting and retaining scientists in the present competitive market. This problem has been magnified in recent years by budget shortages which, happily, are now beginning to be alleviated in the current expansion program. We have had difficulty in obtaining adequate quarters and funds for up-to-date modern laboratory equipment. We expect that the contemplated expanding budgets will provide the means to solve the equipment problem and that in due time the authorized new building will provide the needed quarters.

The Bureau of Biological and Physical Sciences is primarily responsible for most of the scientific research of the Food and Drug Administration. The Bureau consists of seven laboratory divisions. The area of responsibilities and scope of activities are fairly well indicated in the names of the divisions.

The Division of Antibiotics is responsible for the operation of the program of certification of those antibiotics which by law are required to be certified before distribution in commerce. An extensive research program is conducted by this division to provide the basis for proper specifications, methods of analysis and the basic information necessary to appraise the safety and efficacy of these products.

The Division of Cosmetics is concerned with the development of methods of analysis and data for appraising cosmetics. This division also is charged with the responsibility of conducting the coal-tar color certification service. Research programs designed to study the chemistry of the coal-tar colors provide bases for adequate specifications and methods of analysis for checking batches presented for certification.

The Division of Food is responsible for the scientific studies required in this subject-matter area.

The Division of Microbiology is responsible for the bacteriological and microscopic analytical work.

The Division of Nutrition is concerned with studies related to the nutritive values of food. This division is responsible for developing scientific information for the purpose of evaluating claims made with respect to the nutritional value of foods and has provided many of the methods of assay that are now generally accepted for the detection and measuring of vitamins.

The Division of Pharmaceutical Chemistry is responsible for development of methods for drugs and pharmaceutical preparations.

The Division of Pharmacology is primarily concerned with assuring the safety of foods and drugs. It performs a wide variety of biological work involving all categories of products coming within the purview of the FDA.

A few examples of the types of research conducted in our laboratories may be of interest:

(1) Continuing studies are necessary with respect to the normal ranges of composition of food products to develop information that will assist in establishing standards of identity and standards of quality and fill of container. Research in this area also is conducted to provide methods that will enable detection of deviations from the standards.

(2) Research has been conducted to investigate the chemistry of decomposition of foods—to identify the products of decomposition and to develop objective methods of gauging the fitness of food. This research has been particularly fruitful in providing the basis for more effective regulatory appraisal of dairy products and fishery products. The methods and findings produced by these researches which have been made available to the industries concerned have assisted them in improving their products through more adequate manufacturing and laboratory controls.

(3) We are conducting research in the chemistry of pesticide residues, preservatives, and other food additives, directed toward development of methods of analysis that can be depended upon to identify and accurately measure residues of such chemicals. This work is essential in our appraisal of petitions requesting the establish-

ment of tolerances for various pesticide chemical residues. It is of primary importance that, in setting a tolerance, we be certain of the identity of the residue and the magnitude likely to be incurred from the intended use of the pesticide chemical in order to judge the practicability of the tolerance.

(4) One of our most important and difficult responsibilities is the evaluation of the safety of tolerances for pesticide chemicals on raw agricultural products. Petitioners are required to submit toxicological data with respect to the chemicals for which they seek tolerances. This includes feeding tests on laboratory animals. Our scientists appraise the petitions to determine if the data are adequate to show that the tolerance levels sought are safe. This involves the application of responsible scientific judgment in interpreting the animal tests in terms of probable effect on another species—man. Margins of safety must be applied because there are many factors that make absolute certainty impossible.

Hence, we are conducting much research in the study and development of procedures for measuring toxicity and interpreting the results of pharmacological experiments. This work is not only essential to enable the establishment of safe tolerances for pesticide chemicals, but also for the adequate appraisal of food additives of various kinds, including coal-tar colors.

(5) The appraisal of proposed tolerances of pesticide residues in forage crops involves not only determination of the safety to the animals but also requires consideration of the possible introduction of residues of the chemical into the food products of the consuming animals, such as meat, eggs, milk. What happens to a pesticide chemical when it is consumed by a cow? We have conducted investigations along this line and have found out some very interesting facts with respect to certain classes of pesticide chemicals. Some chlorinated hydrocarbons, such as DDT, accumulate in the fatty tissues of the animal and appear in the milk. There is no threshold level below which it will not appear in the milk. Other chlorinated hydrocarbons may be present in the forage to some extent without appearing in the meat or the milk. Research of this sort is essential to enable intelligent and accurate administration of tolerance-making responsibility if the tolerances established are to be truly safe, as the law contemplates.

(6) It is known that prolonged heating of fats and oils causes certain changes in molecular structure. Our Divisions of Food and Nutrition are conducting research to investigate the nature of these changes to determine their significance as to possible toxicity or effect on nutritive values. Work also is being started to develop methods of measuring protein quality. The possible relationship and significance of nutritive factors, such as unsaturated fats, in disease will be discussed by our Medical Director.

(7) A proposal recently has been made that the standards of identity for certain cheeses be amended to admit the use of a peroxide in bleaching the milk used in making the cheese. We are unable to determine whether the proposal would constitute fair dealing in the interest of consumers without knowing what effect, if any, the treatment may have on the nutritive value of the food. Accordingly, some research is under way to investigate the effects of this treatment.

(8) Certain hormones are used in the production of food animals. The addition of such substance to the feed of beef cattle or injection into poultry to promote the growth of these animals has raised questions as to the effect of this treatment in terms of safety of the food products delivered to consumers. Research in this area has resulted in the development of a very sensitive method of assay, capable of detecting fractions of a part per billion of residual hormone activity.

(9) The Howard mold count procedure, developed by B. J. Howard in our laboratories many years ago, is well known to most manufacturers of tomato products as an index of the presence of rot and is a procedure widely used in industry for control purposes. Continuing investigations have broadened the application of this and similar procedures to many types of food products.

(10) Extensive studies have been pursued and are being continued in developing data on the physical structure of insects to enable the interpretation of microscopical examination of foods. Investigations to establish microanalytical methods that are adequate in identification of plant products are also being pursued. In this field we have had extensive cooperation of industry scientists and the collaboration has been helpful both to the government scientists and to the industry people in improving the handling and preparation of cereal foods and dairy products, particularly.

(11) Recently, a food manufacturer informed us of his discovery of the probable toxic potential of safrol, an ingredient of oil of sassafras, extensively used in flavoring substances. We have started some research to further investigate this matter. In the meantime we have notified all members of the flavoring industry of the facts now available so that the fullest consideration can be given to the problem by all interested parties who have been invited to advise us of any further information that may be in their possession.

It is apparent that we do not lack for interesting and important scientific problems to challenge the professional ingenuity of our scientists. We believe that their work has established sound foundations for the administration of the law and, at the same time, has contributed substantially to the advancement of science. **[The End]**

MISBRANDINGS

by

Arthur A. Checchi

The labeling requirements of the Federal Food, Drug, and Cosmetic Act are designed to insure that food is truthfully labeled and that the information which Congress believes the consumer wants and is entitled to have appears conspicuously on the label. It would be presumptuous of us at this time to recall to your attention each of these requirements. They are well known to you. However, there are certain problems which we might profitably discuss.

Let us consider the section of the law that declares a food misbranded if its labeling is false *or* misleading *in any particular*. The major problems in this area of labeling today are created by those firms that through the careful use of half truths and innuendo exploit the gullibility, imagination or unwariness of consumers. This results in labeling that is very carefully calculated to lead the consumer to reach independent conclusions about the relative merits of a food that neither could be, nor are, stated outright in the labeling.

The opportunist, who wishes to seize and capitalize on a current public whim, and the so-called food quacks are the primary offenders in this area. Time was when basic food products were sold because of their nutritive value only. Their labeling representations were pri

marily geared to that point. Now certain segments of industry—presumably in order to boost sales and meet competition—are swinging into other directions. The food quack boldly preaches that all disease is caused by inadequate diet and can be remedied only through a corrected diet. His claims are seldom made in labeling, but rather through the door-to-door or lecture technique. We also have the more subtle operators who rise in indignation at the food quacks but, through adroit promotional material and labeling, develop in the minds of purchasers the idea that their products have some special body-building characteristics or value in certain disease conditions. They seldom make a direct claim because they know full well that such a representation would bring swift action against them, whereas it sometimes takes the government longer to develop convincing evidence that the indirect approach is equally misleading. By then the promoter has abandoned that scheme and moved on to another, thus staying one step ahead of the law—he hopes. Then there is the operator who does not trade in therapeutic representations but misleads through other means. For example, the exploitation of one ingredient in a food is designed to lead the consumer to believe that the article is something special. This is usually done to take advantage of some public fancy about that particular ingredient.

We have no doubt that such practices not only cause deception and confusion of the consumer, but create a very serious competitive problem for other manufacturers who may well take the attitude that they must adopt the same practice or go out of business. We wish we could offer a panacea; unfortunately we cannot. We bring legal actions, involving the most serious misbrandings, but they have not yet brought the improvement needed. We hope that through other means a greater degree of compliance with the prohibition against false and misleading representations in labeling can be achieved. Perhaps the answer lies in a more careful evaluation of labeling by persons in industry responsible for over-all management and legal compliance rather than leaving the matter in the hands of persons whose primary function is selling and whose knowledge of legal requirements is only coincidental.

One of the significant features of the 1938 Act is that section of the law which permits the Secretary of Health, Education, and Welfare to fix food standards whenever in his judgment it will promote honesty and fair dealing in the interest of consumers. The standard-

making procedure since has been materially simplified by the passage of the Hale Amendment, which permits the formulation and revision of standards without hearing procedures in cases where there is no controversy. If there is no controversy, this does speed up the process. If controversy develops, there is no significant speed-up. Several proposed standards are in controversy now.

Obviously, once a standard has been established, in order to be effective and meaningful to the consumer as well as to industry it must be observed rigidly. No deviations, other than those allowed by the regulations, or special permits, for experimental packs, can be tolerated. Otherwise, the confusion and deception that will arise will contravene the basic purpose of creating honesty and fair dealing. The special permits are designed to afford manufacturers opportunities to test market experimental packs of products which purport to be, and are labeled as, standardized items, but which differ in some particular. This allows the manufacturers to determine consumer acceptance and provides valuable information for use in deciding whether the standard in point should be amended.

What a Standardized Food Should Be

It has always been our view that if an article purports, or is represented to be, a standardized food, then by statute it must comply with all the requirements of the standard, regardless of its labeling. We extended this philosophy to products that failed to meet the standards and were labeled as imitations. This position was reversed by the Supreme Court, which ruled that such an article could properly be labeled as an imitation.

There are presently a substantial number of foods that are imitations of standardized articles, and so labeled, on the market. We do not know the extent to which they depress the market for standardized commodities nor the degree of deception if any, to the consumer. This is a phase of standards work in which we are interested, but not presently active. However, the standard-making, revision and enforcement programs in general, are going forward at an accelerated pace. The Food Standards Committee, composed of federal and state enforcement officials, has been re-established. Our own facilities and staff for this work is also expanding. Unless we are bogged down in hearings, we expect considerable activity in the standard-making field during the coming years.

You will be interested in our latest project in the labeling field. This is a regulatory program to look into and correct any serious abuses that may exist with respect to the lack of prominence and conspicuousness of mandatory information on labels. The law requires that mandatory statements be placed on the labeling in such manner that it will be likely to be read and understood by the ordinary individual under customary conditions of purchase and use. We intend to evaluate current practices and take appropriate action against those products which disregard this requirement. We think it would be advisable for food manufacturers in general to review their labeling from this standpoint to make certain that mandatory labeling is being given the prominence that the law requires.

We are also hopeful that our expanding staff and programming will afford us more time to deal with deceptive packaging. Some study is being given to this already.

We cannot quarrel with the desire of any manufacturer to stimulate sales and outsell a competitor. However, when the sales effort causes deception of the consumer, the point has been reached where the means do not justify the end and corrective action must be taken.

We recognize that there are many instances where a manufacturer may have reservations as to the suitability of certain labeling, particularly with respect to the promotional material. We do not wish to set up the Food and Drug Administration as the conscience of industry or the tsar of labeling; such is not its function. However, we are entirely willing to express our administrative views on labeling problems put to us. Needless to say, these are advisory only and always subject to judicial review. We are certain that you join in our desire to make certain that food products are properly labeled and that the American consumer should not have to be an expert in critical label analysis to evaluate the real worth of an article he contemplates purchasing. **[The End]**

CONCLUDING STATEMENT

by

George P. Larrick

In 1955, the citizens advisory committee that studied the Food and Drug Administration made 140 individual recommendations, many

of which were interrelated. We have acted completely or substantially on 56. We have made progress on 75 others; generally further progress on these is directly related to future increases in appropriations.

Some of the more important accomplishments and goals for the future follow:

(1) We are expanding, and we hope the expansion will continue as recommended by the advisory committee.

(2) We have effected a basic reorganization, placing the Washington laboratory divisions in a single bureau and establishing four other bureaus.

(3) We have strengthened the office responsible for program management. It is now a bureau, with increased responsibilities.

(4) The General Counsel's Office has expanded its food and drug division. Future growth of the legal staff should be at a greater rate than that of the Food and Drug Administration because of the more diversified legal problems that will develop from the expanded programming now under way.

(5) We are expanding facilities for public information and education.

(6) We want to use more outside scientific facilities to solve technical problems. This would enable us to supplement the scientific data developed in our laboratories with results of research conducted elsewhere—in educational institutions, for example.

(7) We need to pay top scientists super-grade salaries that are more in keeping with their true worth. We are in competition with other government agencies and industry in recruiting scientists, but our pay scale is well below that of industry and for key personnel is even below the pay scale in a number of sister government agencies. The competence of our professional staff will be directly related to the quality of service that we can perform for consumers and honest business.

(8) We need adequate space and equipment. In Washington, we are spread out in three buildings, each several blocks away from the others. The laboratories in the South Building of the Department of Agriculture are old. We have preliminary plans for a new FDA building, but all progress has stopped on it now. It was to be a lease-purchase building, and the Congress specified in our last appropriation act that none of the money should be used to pay the salary of any person who planned for a lease-purchase building.

In summary, we are making substantial progress in achieving the goals recommended by the citizens advisory committee. The present organization will support future growth and, if we continue to get favorable appropriations and improve our ability to attract and retain qualified professional employees, we should be able to reach the important goals that lie ahead.

Coming back to the present for a moment, we hope your visit here today will answer the broad questions you have about FDA and its plans for the near future. **[The End]**

PRICE DISCRIMINATION—HAIR AND SCALP PREPARATIONS

A manufacturer of hair and scalp preparations has been prohibited from discriminating in price among its various wholesale customers. The Federal Trade Commission approved a consent order to that effect and adopted an initial decision by a hearing examiner, which contained an order agreed to by the company and the Commission's Bureau of Litigation.

A Commission complaint, issued last March 18, charged the manufacturer with discriminating in prices to different wholesalers. Specifically, the complaint said, some wholesale customers received—in addition to the customary 15 per cent discount—a 10 per cent discount, designated a "warehouse allowance." Other wholesalers, in competition with these favored customers, according to the complaint's allegation, did not receive the additional allowance. The effect of this discrimination, the complaint stated, might lessen competition or create a monopoly in violation of Section 2(a) of the Robinson-Patman Amendment to the Clayton Act.

The complaint further charged that some retailers, in order to buy directly from the company, were required to purchase in at least specific minimum quantities, while favored retailers might purchase directly in any quantity they desired. This practice, the complaint alleged, suppressed competition and was an unfair competitive method in violation of Section 5 of the FTC Act.

Under the provisions of the order, the manufacturer must charge the same prices to all customers who compete with each other in selling the preparations. In addition, minimum purchase requirements must be the same for all competing customers.

The agreement is for settlement purposes only, and does not constitute an admission by the company that it has violated the law. (Released December 9, 1957.)—CCH TRADE REGULATION REPORTS ¶ 26,886.

The Labeling

of Dangerous Household Chemicals

By C. JOSEPH STETLER and BERNARD E. CONLEY

This Paper Describes American Medical Association Activities Connected with Preparation of a Suggested Model Law Dealing with Labeling of Poisonous Household Chemicals. Mr. Stetler Directs the Association's Law Department; Dr. Conley Is Secretary of Its Committee on Toxicology

AMONG the man-made diseases resulting from technical advances in agriculture, in industry and in household conveniences are many forms of poisoning. Unfortunately, many of the chemicals which have been developed to increase the comforts of modern living have injurious effects when they are injudiciously used. It is difficult to be conversant with the composition and possible harmful effects of these products. Physicians and persons attempting to administer first aid are often at a loss as to proper methods of treating poisonings because of the newness, variety, and oftentimes unrevealing character of the contents, of these products.

It is generally agreed that inadequate labeling of potentially harmful chemicals is a major handicap to a successful attack on the problem of accidental poisoning.[1] Although the producers of the products may be willing to provide product composition and an estimate of the dangers involved, they cannot always be reached because of an insufficient label address or because the emergency has occurred at night or on a weekend or a holiday. Lack of information about hazardous ingredients in such emergencies may enhance the gravity of the injury by complicating or delaying treatment. We recognize that precau-

[1] I. Kerlan, in report to the Committee on Toxicology, American Medical Association: "Health Problems Occurring from Household Chemicals, Including Drugs," 163 *Journal of the American Medical Association* 1254 (April 6, 1957).

tionary labeling alone won't insure safety. Nevertheless, it is the keystone to consumer education in the careful use of chemical products.[2]

To put this matter in its proper perspective, we should first consider the magnitude of the problem of accidental poisoning. The latest published mortality statistics (1955) for the United States reveal that 1,431 persons died from accidental overexposure to packaged chemicals. One quarter of these fatal accidental poisonings by liquid and solid substances occurred in preschool-age children and over 80 per cent occurred in the home. Nonfatal poisonings are estimated to be 100 to 150 times the number of fatalities. These are impressive statistics for a cause of injury and death which is considered to be largely preventable.

Tremendous strides have been made in recent years in reducing mortality from infectious diseases. No comparable improvements have occurred in the prevention of accidental poisoning or in modifying the over-all frequency of fatal injuries from chemicals. A persistently large number of these unintentional intoxications occur among children in the home. Although accidental deaths from falls and burns rank ahead of poisonings in the home, they are also less preventable because of the difficulty in controlling these accidents by anticipatory measures. On the other hand, accidental poisoning—especially among children—can be reduced substantially by comparatively simple precautions when parents are aware of the hazards.

A social study of accidental poisoning has shown that true negligence on the part of parents is not a common cause of poisonings.[3] It was found that most of the children who take poison are active and curious. Most of the substances ingested by the children reported in this study were easily accessible to the young victims. It was further found that parents did not realize that a number of common household substances are poisonous until after the accidents occurred. This is an affirmation of our belief that more intelligent use of chemicals in the home will result from the user's consciousness of possibly harmful ingredients and of the risks attendant on misuse.

The Committee on Toxicology of the American Medical Association considers the use of precautionary labeling of potentially harmful household and commercial chemicals as a needed deterrent to carelessness in their handling and storage. Last year, the Board of Trustees of the American Medical Association authorized the committee to

[2] J. C. Ward, "Labeling," proceedings of the Chemical Specialities Manufacturers Association, 39th Midyear meeting, Chicago, May, 1953.

[3] J. Beveridge, "Accidental Poisoning in Childhood," 1 *Medical Journal of Australia* 216 (February 11, 1956).

develop, in collaboration with other interested and informed groups, a "model law" for the labeling of the many possibly harmful chemical products not now so regulated. The proposed legislation is intended to close the gap in the pattern of regulations requiring precautionary labeling and the identification of hazardous ingredients.

Historical Background

The medical profession's recognition of the need for precautionary labeling first became evident nearly 75 years ago. In 1884, the American Medical Association adopted a resolution urging that Congress and the various state legislatures be called on to enact legislation to require lye to be sold as a poison, under a "poison" label. Later resolutions were adopted, in 1910 and 1918, urging the proper labeling of caustic poisons. These actions culminated in the formation of a committee to obtain legislation regulating the sale of caustic products under the chairmanship of Dr. Chevalier Jackson, a noted otolaryngologist of Philadelphia.

In 1923, the House of Delegates of the American Medical Association adopted a resolution which called attention to the fact that the domestic use of concentrated lye and other caustic alkalies and corrosive substances was a not-infrequent cause of death and distressing disability among children. The house recommended that, in the interest of public health and safety, the packing, labeling and distribution of such substances should be regulated by law. A special committee on lye legislation was created. The bureau of legal medicine (predecessor of the law department) collaborated with this committee and prepared a model state law and a bill for introduction in Congress.[4] The federal law was enacted in 1927, and the model state bill—uniform with the federal law—has since been enacted in a number of states. Since these bills were drafted, many new chemicals have been introduced which are outside of their scope.

The recent approval by the Board of Trustees of the American Medical Association of the recommendation of the committee on toxicology that a uniform chemical label law for dangerous household and commercial chemicals be prepared is well supported by other historical precedents.

In 1848, the American Medical Association and the New York and Philadelphia Colleges of Pharmacy successfully petitioned Congress

[4] "Report of the Committee on Lye Legislation," transactions of Section on Laryngology, Otology and Rhinology of American Medical Association, p. 11 (1910); p. 13 (1918); p. 8 (1919); p. 15 (1921); p. 12 (1923); p. 11 (1929).

for the passage of the Edwards bill, prohibiting the importation of adulterated drugs. This law led to the eventual enactment of the first Federal Food and Drugs Act in 1906. *The Journal of the American Medical Association* of August 4, 1906, after commenting favorably on the passage of this federal legislation, said: "Uniform State Pure Food and Drug Legislation is now needed."

On the occasion of the fortieth anniversary of the original Federal Food and Drugs Act of 1906, Dr. Rober I. Lee, then President of the American Medical Association, said in May, 1946:

> The American Medical Association played a leading part in the development of the original Act and has supported the various changes which experience and the remarkable progress of medical science have necessitated in the Act . . . . It is most fortunate that the original Act, excellent as it was, did not become static. From time to time, the Act has been amended as the necessity arose and the newer regulations have kept the purpose of the Act in step with medical progress . . . .
>
> A single item, which is of great interest and benefit to the Medical Profession, may be cited; namely, the trend towards informative labeling. With the present flood of new drugs, some of which are very potent, both the physician and the patient are often greatly benefited by the extension of regulations in regard to labeling.

In 1892, the American Medical Association made the first proposals for suitable food and drug legislation. It recommended, in that year, the establishment of a department of health to accompany a Food and Drug Administration, both of which have since evolved. In 1906, the Congress passed the first federal legislation in the "patent medicine" field—the Federal Food and Drugs Act. The law did not require the declaration of any ingredients of a nostrum on the label, except alcohol and 11 narcotic drugs or their derivatives. It did, however, cover cases involving false and fraudulent claims on the label or carton and in accompanying circulars. In 1933, the board of trustees of the AMA became interested in the food, drugs and cosmetics bill. The board adopted the following resolution:

> Resolved, that the American Medical Association pledges its support toward procuring the formulation and enactment of effective national food and drug legislation adequate for the protection of the public.

The Federal Food, Drug, and Cosmetic Act was passed by the Seventy-fifth Congress and approved by the President on June 25, 1938.

Existing Labeling Laws

An article outlining in detail the pattern of existing chemical labeling laws was published recently in the *Journal of the American*

Pharmaceutical Association.[5] Briefly, informative labeling of chemicals is required by seven major types of laws. These laws require highly toxic products to be identified by the skull and crossbones on the label while, in cases of less dangerous products, they require identification of the hazardous or active ingredient and warnings against injury under ordinary use.

At the national level, label laws exist for drugs, pesticides, caustic and corrosive substances, and narcotics. No nation-wide law exists for the precautionary labeling of industrial chemicals, household chemicals or poisons. In addition, the Interstate Commerce Commission and the Post Office Department issue regulations regarding the packaging and labeling of chemicals in transit by land or water or via the mails.

State legislation is a patchwork of laws patterned after (1) existing federal legislation, (2) earlier, but now superseded, federal statutes and (3) special laws which are often overlapping. Sixteen types of special laws for chemicals are in force in various states, some of which have as many as five such statutes. Other states have either inadequate regulations or no regulations at all. A condensed table of existing labeling laws for chemicals accompanies this article.

Various attempts have been made in recent years to extend the scope of existing legislation to require precautionary labeling of potentially harmful chemicals in commerce. The first of these attempts was the Bingham bill of 1932, which called for the labeling of certain chemical products, particularly those evolving injurious vapors. This bill aroused chemical manufacturers to the need for developing a program for adequate labeling. A series of voluntary agreements between the manufacturers of six groups of chemical products and the United States Public Health Service was proposed and accepted in 1934 in lieu of federal labeling legislation. The manufacturers agreed to specific warning labels for shipments of the following chemical products: methanol, carbon tetrachloride and related volatile chlorinated hydrocarbons, chlorinated naphthalenes, diphenyls and their oxides, carbon disulfide, benzene, and nitrobenzene. These agreements were discontinued in 1952 because of the introduction of new hazardous chemicals not covered by the agreements and the existence of additional product warning labels over and above those covered by the

[5] B. E. Conley, "The Need for a Uniform Chemical Label Law," 18 *Journal of the American Pharmaceutical Association* 585 (1957).

Condensed Table of Existing Label Laws for Chemicals

	Poison Law	*Poisons in Pharmacy Act*	*Drug Law*	*Narcotic Law*	*Caustics Law*	*Economic Poisons Law*	*Industrial Chemicals*	*Household Chemicals*	*Special Laws*
Alabama	Y	...	Y	X	X	X	...	...	2
Arizona	...	Y	Y	X	X	X*	...	...	...
Arkansas	Y	...	X	X	...	X	...	...	1
California	...	Y	X	Y	...	X	Y	...	1
Colorado	...	Y	Y	X	Y	X	...	...	3
Connecticut	...	Y	X	X	...	Y	...	Y	1
Delaware	...	...	Y	X	Y	*	...	...	1
District of Columbia	...	Y	Y	X	...	*	...	...	...
Florida	Y	...	X	X	Y	X	...	...	...
Georgia	Y	...	Y	X	...	X	...	...	2
Idaho	...	Y	Y	X	...	*	...	...	2
Illinois	Y	...	...	X	...	*	Y	...	4
Indiana	...	...	X	X	...	*	...	Y	1
Iowa	Y	...	X	X	...	Y	...	...	...
Kansas	...	...	X	Y	Y	X	...	Y	1
Kentucky	Y	...	Y	X	...	...	...	...	2
Louisiana	...	...	X	X	Y	Y	...	...	1
Maine	...	Y	Y	X	...	X	...	...	2
Maryland	Y	...	Y	X	Y	Y*	...	...	3
Massachusetts	Y	...	Y	Y	X	Y*	...	...	2
Michigan	Y	...	Y	X	...	X	...	...	5
Minnesota	...	Y	Y	X	X	X	...	...	3
Mississippi	Y	...	...	X	X	X	...	...	3
Missouri	...	Y	X	X	...	X	...	...	...
Montana	...	Y	Y	X	...	X	...	...	...

Nebraska		Y	Y	X	...	...	...	...	1
Nevada	Y	...	X	X	X	X	...	...	...
New Hampshire	...	...	X	Y	Y	X	...	...	2
New Jersey	...	Y	X	X	Y	X	Y	...	1
New Mexico	Y	...	X	X	...	X	...	...	1
New York	Y	...	X	X	Y	X	Y	Y	1
North Carolina	...	Y	X	X	...	X	...	...	2
North Dakota	Y	...	Y	X	...	X	...	...	1
Ohio	Y	...	Y	X	Y	*	...	...	3
Oklahoma	...	Y	X	X	...	X	...	...	3
Oregon	Y	...	...	X	Y	X	Y	...	1
Pennsylvania	Y	...	Y	Y	X	Y	...	...	5
Rhode Island	...	Y	Y	X	Y	X	...	...	2
South Carolina	Y	...	Y	X	Y	X	...	...	2
South Dakota	Y	...	Y	X	...	X	...	...	2
Tennessee	...	Y	X	X	...	X	...	...	2
Texas	Y	...	Y	X	...	Y*	...	...	1
Utah	...	Y	Y	X	...	X	...	...	...
Vermont	...	Y	Y	X	X	X	...	...	1
Virginia	Y	...	X	X	X	X	...	...	...
Washington	Y	...	X	Y	X	X	...	...	...
West Virginia	Y	...	Y	X	Y	X	...	...	...
Wisconsin	...	Y	Y	X	Y	X	...	...	...
Wyoming	...	...	Y	X	...	X	...	...	...
United States	...	...	X	X	X	X	...	...	...

*—does not include household pesticides.
X—similar to federal law.
Y—individual state law.

Percentage of States Covered by Laws

Narcotics	—100%	Caustics	— 52%
Drugs	— 93%	Industrial Chemicals	— 10%
Poisons	— 89%	Household Chemicals	— 4%
Pesticides	— 85%		

original agreements. This program served to focus attention on the need for a sustained, dynamic program for the development of precautionary labeling for hazardous chemicals.

In spite of this attempt and subsequent attempts to provide warning labels, the labeling of hazardous products has been "sketchy and unpopular," according to the secretary of the Manufacturing Chemists Association.[6] He stated:

> The few regulatory requirements in the field suffered from lack of uniformity and took no recognition of relative degrees of hazard. While certain chemicals were being pointed to as "villains," many other more hazardous materials were being happily distributed with no recognition of their dangerous properties. Meanwhile, the organic insecticides and other new and useful products possessing hazardous characteristics were being synthesized by the chemical industry and markets were being developed.

Recently, a bill for the enactment of a "Federal Dangerous Articles Act" was introduced by Senator Prescott Bush in the Eighty-fourth Congress. Substantially the same bill (Bush bill, S. 1900) was again presented, on April 16, 1957, to the Senate in the Eighty-fifth Congress. On May 9, 1957, Congressman Curtis of Missouri introduced a similar bill (Curtis bill, H. R. 7388) to the House of Representatives. The bill proposes to regulate the interstate distribution and sale of packages of hazardous substances intended for household use. The labeling required by the bill would carry (1) such words as "dangerous," "warning," "caution" and "keep out of the reach of children" and (2) information as to emergency first-aid treatment to minimize any injury inflicted, until medical attention could be secured. Its author describes it as an extension of the Federal Caustic Poison Act of 1927.

Model Law

A model law to require label information on hazardous ingredients and precautionary measures for household and commercial chemical products has been under consideration by the American Medical Association for some time. A 1951 resolution of the American Medical Association House of Delegates called for a general study of the problem. This led to the formation of the committee on toxicology. As indicated earlier, the American Medical Association Board of Trustees last October authorized this committee to draft a model law for the labeling of hazardous chemicals not now so regulated. Tentative provisions for a uniform chemical label law were reviewed, at the

[6] M. F. Crass, "Labeling Principles and Problems," official publication of the Association of Economic Poisons Control Officials, 1953, at p. 48.

annual meeting of the American Medical Association Committee on Toxicology, on March 29, 1957. It was the committee's recommendation that a legislative conference of interested parties in government, industry and medicine be called some time this fall. The purpose of this conference will be to obtain agreement, or provide a mechanism whereby agreement may be obtained, on the final provisions of a model law.

The legislation contemplated by the American Medical Association is intended to make the public aware of these and other potentially harmful products which are commonly found or used in the home and in small business establishments, and to encourage careful handling and storage of such products. Fundamentally, the model uniform law will require the informative labeling of hazardous household chemicals, including the listing of possibly harmful ingredients, their potentialities for harm, directions for proper use, and emergency first-aid instructions.

Although the American Medical Association has on several occasions expressed its opinion on proposed legislation relating to the practice of medicine, it has rarely prepared and recommended model legislation. Nevertheless, it is felt that the enactment of adequate legislation to assure the proper labeling of household chemical products is a necessary step. Such legislation will undoubtedly be of inestimable value in helping physicians protect the lives and health of the American public. **[The End]**

TWO NEW DRUGS BROUGHT UNDER CONTROL OF FEDERAL NARCOTIC LAWS

According to a release issued by an associate press secretary to President Eisenhower:

"The President signed a proclamation which brings under the control of the Federal Narcotic laws two new synthetically produced drugs, each of which has been found to have addiction-forming or addiction-sustaining liability similar to morphine. The two new drugs are described as:

"1-(2 Morpholinoethyl)-4-carbethoxy-4-phenylpiperidine.

"*d*-2, 2-Diphenyl-3-methyl-4-morpholino-butyryl-pyrrolidine.

"This proclamation insures the application, to each of the new drugs with their dangerous addiction potentiality, of the same restrictive measures as are applied to morphine and similar addicting derivatives of opium."

The release was dated December 11, 1957. The proclamation was published at 22 *Federal Register* 10025 (December 14, 1957).

Substitution as "Gross Immorality"

THE TERM "substitution," as generally defined and as used in this article, means, simply, the unauthorized dispensing of a drug or a brand of drug other than that which is ordered or prescribed. This definition embraces two elements. First, the drug or brand of drug furnished by the pharmacist must differ from the drug or brand called for. Second, this departure from the terms of the order or prescription must be without the express consent of the orderer or prescriber. As thus defined, substitution may take place with over-the-counter products as well as with "prescription only" preparations.

Although there is evidence that substitution existed as long ago as the eighth century B. C.,[1] it probably was never more prevalent than in the early years of the present decade. This is not to say that the practice has found acceptance among pharmacists generally. On the contrary, the number of substituting druggists appears to be relatively small. Moreover, there are indications that the past few years have witnessed a decided decrease in the practice of substitution.[2]

Credit for this recent decline must go to the boards of pharmacy and similar licensing agencies throughout the country. Other approaches to the problem had been tried, but with little success. Private unfair-competition suits against manufacturers of "counterfeit" preparations, while generally successful, proved almost prohibitively expensive and time-consuming. Furthermore, when an injunction was obtained against one manufacturer, another would quickly appear to take his place. The process became endless. Private suits against substituting pharmacists met with the same unsatisfactory results. Food

[1] Otto Raubenheimer, in a paper presented at the 1916 meeting of the American Pharmaceutical Association, traced substitution to the year 880 B. C.

[2] A 1957 poll of manufacturers of drug specialties conducted by the American Druggist Magazine puts the current rate of substitution on prescription at 3.7 per cent as contrasted with a 14.7 per cent rate in 1953.

By JOHN J. GALBALLY

The Author—Staff Attorney, Smith Kline & French Laboratories—Views the Dishonest Practice of Drug Substitution in Light of Tests for Gross Immorality Specified in the Case of *Indiana Board of Pharmacy v. Haag*

and drug enforcement agencies lacked both the personnel and resources to deal effectively with the problem.

With the alarming rise in the rate of substitution in the early 1950's, interested segments of pharmacy turned to the pharmacy boards as the most logical and best-equipped agencies to combat the growing menace. Few pharmacy boards at that time had specific statutory authority to deal with substitution. On the other hand, nearly half had power to suspend or revoke the license of a pharmacist who was found guilty of "gross immorality" [3] or its substantial equivalent.[4]

Quite naturally, the question was asked: Does substitution come within the term "gross immorality"? At first blush, the answer to this question might appear to be in the negative. However, an analysis of the nature of substitution in light of the decided cases construing the statutory term lends considerable support to a different conclusion.

Definition of "Gross Immorality"

In certain contexts, the term "gross" may mean great, excessive, coarse or vulgar. The term "immoral" also has many shades of meaning. Because of this, it is important at the outset to show precisely what the words signify in pharmacy statutes of the kind in question.

[3] The pharmacy statutes of the following states contain a "gross immorality" provision: Alabama, Arizona, California, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Missouri, New Hampshire, New York, North Carolina, Ohio, Washington, West Virginia and Wyoming; the South Carolina Board of Pharmacy has promulgated a regulation employing the term.

[4] The laws of Iowa, Nebraska and New Mexico provide for suspension or revocation for "immoral conduct," those of the District of Columbia for "immoral character."

The leading authority is the case of *Indiana Board of Pharmacy v. Haag*[5] decided by the Supreme Court of Indiana in 1916. There the pharmacist's certificate of registration had been revoked under a "gross immorality" statute for selling liquor without a license. In affirming the revocation, the court said:

> Immorality, as defined by Webster, is "the quality of being immoral;" "an immoral act or practice." . . . Immoral [as defined by law writers], as that which is "hostile to the welfare of the general public * * * ;" "wicked;" *"unjust;" "dishonest;" "vicious;" "unjust in practice."* . . .
>
> *"Gross," as used to modify the word "immorality," does not mean great or excessive, but rather "willful, flagrant, or shameless,* showing a moral indifference to the opinions of the good and respectable members of the community . . . and to *the just obligations of the position held by the delinquent."* (Italics supplied.)

This famous and often-quoted passage has since been approved and adopted by the Indiana Legislature by incorporating it almost verbatim in the statute regulating the practice of dentistry in that state.[6]

Substitution, and Position Held by Pharmacist

As indicated in the *Haag* case, in determining the standards to which the pharmacist must be held, his status in the community is an important factor. His position is one of unusual trust and responsibility, since the health of most members of the public is at one time or another dependent on his care.

Because of this unique position, laws have been passed in each state restricting the practice of pharmacy to persons of skill and integrity. These laws usually take the form of licensing measures requiring that all pharmacists in the state register with a board of pharmacy.

Invariably, a number of severe conditions for registration are imposed. For example, the applicant for registration must meet increasingly stringent educational requirements. In addition, he must satisfy the board of pharmacy that he is qualified in chemistry and other highly technical subjects by passing an examination in the theory and practice of pharmacy.

Once registered, the pharmacist must continue to demonstrate his fitness by observing certain moral and ethical standards consistent

[5] 184 Ind. 333, 338, 111 N. E. 178. See also *Klafter v. State Examiners*, 259 Ill. 15, 102 N. E. 193 (1913). For an interesting discussion of the *Haag* and related cases, see the article entitled "Revocation of License for Gross Immorality," by Albert Woodruff Gray, appearing in the February, 1955 issue of *The American Professional Pharmacist*.

[6] Burns Indiana Statutes Annotated, Ch. 5, Sec. 63-518(3).

with his position of trust. If he fails to do so, he may be required to forfeit his license.

The law clearly treats the pharmacist as a professional man.

The professions have standards different from those of ordinary occupations. What is right for a hairdresser, for example, is not necessarily right for a physician. The former may advertise and solicit business through all normal means, the latter may not. "Fee splitting" provides another illustration. Although perfectly permissible in ordinary commercial affairs, this practice is such a serious breach of medical ethics as to warrant revocation of a physician's license.[7]

As stated by the Supreme Court of West Virginia:

> "Gross immorality" should be measured by the standards of each profession, and in this particular profession . . . the standard should admittedly be of the highest, . . . [since] the lives of individuals may depend upon the integrity and honesty of the physician . . . .[8]

Although this statement was made concerning the medical profession, it may be said with equal reason that the standards of the pharmacy profession should be of the highest, since the lives of individuals may depend upon the integrity and honesty of the pharmacist. This is by no means an overstatement when one considers the unprecedented range and potency of modern drugs. Thus it can be seen that pharmacy, like medicine, has no place for the unskilled or the unscrupulous.

Substitution—Obligation of Honest Dealing

The pharmacist's dealings with his customers are on a basis different from that of the ordinary merchant, the nature of whose wares is easy to determine. In the case of prescription drugs, the customer buys entirely on faith. When a pharmacist receives a prescription for a particular brand, he will normally transfer the desired number of tablets or other units from the commercial container to a smaller container furnished by him. As a rule, the label on the druggist's container will not disclose either the identity of the contents or the name of the manufacturer.

It is easy to see that the drug purchaser—unlike the buyer of a television set, an electric toaster or even a package of cigarettes—has no means of knowing whether he has received what he ordered. The result is that the purchaser of drugs is entirely at the mercy of the pharmacist. The need for honesty under these circumstances is overwhelming.

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[7] *Mingo County Medical Society v. Simon*, 124 W. Va. 493, 20 S. E. (2d) 807 (1942), where the license of a medical practitioner was revoked on the ground, among others, of "fee splitting."

[8] Case cited at footnote 7.

Substitution takes on an additional aspect where the substitute article is a deliberate copy—a counterfeit—of the product of a reputable manufacturer. The added vice of this type of substitution lies in the fact that even those who are familiar with the product are deprived of the means of detecting the fraud. This "palming off" type of substitution has been characterized by one federal court as follows:

> In ordinary commercial affairs, "substitution by deception" is wrongful, but, when in the healing art there is "substitution by deception," greed may reach the grade of malice.[9]

Substitution and Unjust Enrichment

We now come to the substituting druggist's motive. The motive in most cases is profit, pure and simple. The so-called miracle drugs and revolutionary forms of medication which have emerged from the laboratories of the pharmaceutical industry have been produced at great cost. They are sold to the public at prices which will compensate drug manufacturers for their research expenditures. This sets the stage for competition on a price basis. The second comer, having no research expense and reduced promotion costs, can afford to sell the drugs at a lower price.

Unfortunately, certain drug manufacturers are not content with this legitimate competitive advantage. These manufacturers produce imitations and counterfeits of drugs put out by reputable concerns, often at a fraction of the cost to the latter. These imitative products are purchased by a minority of unscrupulous druggists with the intention of palming them off for the genuine when the latter are ordered. The price charged for the spurious product is invariably the price commanded by the genuine article, the difference being pocketed by the substituting druggists.

The courts have not hesitated in their handling of similar schemes for unjust enrichment. For example, in the Ohio case of *Rose v. Baxter*,[10] a physician who maintained two different offices under two different names for fraudulent purposes was held guilty of gross immorality.

In a recent Indiana case,[11] a physician's license was revoked for gross immorality upon a showing that he had treated a patient for diabetes by means which he knew could not work a cure. The Indiana Supreme Court in that case reached the following significant conclusion:

[9] *Winthrop Chemical Company v. Weinberg*, 60 F. (2d) 461, 463 (CCA-3, 1932).

[10] 7 Ohio N. P. (n. s.) 132, 18 Ohio Dec. N. P. 658 (1908).

[11] *Board of Medical Registration & Examination v. Kaadt*, 225 Ind. 625, 76 N. E. (2d) 669 (1948). See also 219 Ind. 191, 37 N. E. (2d) 65 (1941), and *Brown v. Hassig*, 136 Kan. 384, 15 Pac. (2d) 401 (1932).

In order for the evidence above set out to establish gross immorality we must conclude that it is sufficient to support the inference that the practice complained of was not an honest effort on the part of the appellee [physician] to relieve suffering but was a scheme for his unjust enrichment.

Substitution and General Welfare

Substitution may take either of two forms. In the one case, the druggist will substitute a drug which differs fundamentally from the one ordered or prescribed. The danger to the patient's health from substitution of this type need hardly be commented on. The second type of substitution involves the use of a brand different from the one that has been prescribed. The two products ostensibly contain the same active ingredient or ingredients. The pharmacist detected in this practice will attempt to minimize the seriousness of his conduct by stating that "one brand is as good as the next." Such statements are open to serious question.

In the first place, different brands of the same drug have been known to produce different effects, including different degrees of side reaction, probably because of variations in manufacturing technique. In the second place, the reliability or lack of reliability of the manufacturer is of the highest importance. That some manufacturers fail, at least occasionally, to use proper manufacturing controls is demonstrated by the number of proceedings successfully prosecuted under Section 501(c) of the Federal Food, Drug, and Cosmetic Act. Consequently, many cases of substitution have been reported where the "same" drug contained a significantly, and sometimes drastically, different dosage than that set forth in the manufacturer's label. Other instances may be cited where the actual chemical ingredient of the drug was other than as represented.[12]

[12] The following are some examples of dangerous substitutes which have been marketed in recent years. This information is based upon the official Notices of Judgment Under the Federal Food, Drug and Cosmetic Act and, in one or two instances, upon reports from pharmaceutical manufacturers. See, also, "Are Your Patients Getting Counterfeit Drugs?" in the September, 1954 issue of *Medical Economics*, at p. 133.

Genuine	*Substitute*
Cortisone acetate	Ascorbic acid
Aureomycin	Bismuth subgallate
Gantrisin Syrup	Unknown sulfa preparation
Methyl testosterone, Ciba	Starch
Neo-Synephrine	Ephedrine
Neo-Synephrine	Unknown substance causing ulceration of tissue
"Enseals" of ammonium Chloride (four-hour delay)	Tablet which failed to disintegrate
Sustained-release medication (eight hours	Preparation released in one-half hour
Amphetamine sulfate	Desoxyephedrine hydrochloride
Premarin	Imitation containing no conjugated water-soluble estrogens
Dexedrine	Imitation varying 40 per cent in strength
Dextro-amphetamine sulfate capsules (15 mg.)	Product containing 15 per cent of declared amount of drug

There are, of course, particular areas where the skill of the maker assumes added importance. Delayed-action medication, for example, has made new demands upon the ability and know-how of the manufacturer. Special coating techniques provide for the release of the drug after one or more intervals or at a uniform rate over a period of many hours.

In the case of enteric coated tablets, anything short of the highest manufacturing skill in making a properly dissolvable product will result in the patient's being deprived of the benefit of the drug. In the case of sustained-release or repeat-action medication, the too-sudden release of an abnormally high dosage of the drug may result in serious consequences to the patient.

Pharmacists can seldom, if ever, assay prepackaged pharmaceutical preparations to determine whether they meet the representations made by the manufacturer. The reliability of the manufacturer is, therefore, of paramount concern to the patient and his physician.

The pharmacist who substitutes on prescription in effect overrules the physician's order for a particular drug or brand of drug. He does so at the risk of interfering with the treatment of the patient. The danger is there whether the substitution involves a different drug altogether or simply the product of a different manufacturer.[13] Clearly, this is inimical to the public welfare.

Conclusion

It can be argued with considerable force that substitution meets every test specified for gross immorality by the case of *Indiana Board of Pharmacy v. Haag,* discussed at the outset.

Substitution, wilfully engaged in, is clearly contrary to the obligations inherent in the pharmacist's position. It is a dishonest practice, resulting in the pharmacist's unjust enrichment. Finally, substitution endangers the health of the patient and, consequently, is hostile to the public welfare. **[The End]**

[13] On September 5, 1956, the Attorney General of the State of Michigan issued an opinion—No. 2766—on the subject of substitution. The National Pharmaceutical Council has recently issued a pamphlet bearing the title *24 Reasons Why Prescription Brand Names are Important To You* also having a bearing on this subject. These tend to the conclusion that there is no real difference between brand substitution and drug substitution as far as public health is concerned.

CHRISTOPHER

COMMENTS

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Lack of Negligence in Implied Warranty.—

Neither allegations of contributory negligence nor those negativing any possible carelessness on the part of defendants are an answer or defense to an action to recover on a breach of an implied warranty.

This traditional doctrine has been applied by a Kansas court.[1] The facts of the case show that the plaintiff purchased a bottle of soda pop from a vending machine at a service station. An employee of the station inserted a coin and opened the bottle for the plaintiff. A few minutes later, it was noticed that the bottle contained a foreign substance—the bottle being shown to the operator of the station.

In an implied-warranty action, the state supreme court applied the above rule and held that the defendant was precluded from putting on evidence to show lack of negligence. The court also ruled that, in order "for defendant to avoid liability under its warranty, it must show who contaminated the beverage and not merely that the defendant itself did not."

The court states further:

A manufacturer, intermediate handler or a retailer-dealer of food for human consumption is, in effect, an insurer that such food will cause no harmful effects because of deleterious matter therein. The basis for imposing this liability is public policy for the protection of the people . . . .

In a tort suit for negligence, evidence of due care would, of course, be admissible.

In the present case, the court holds that the foreign matter was in the bottle when the purchase was made by the plaintiff, and the evidence is convincing in this respect. The only reasonable possibility

[1] *Simmons v. Wichita Coca-Cola Bottling Company*, CCH Food Drug Cosmetic Law Reports ¶ 22,491, 181 Kan. 35, 309 Pac. (2d) 633 (1957).

otherwise was that the plaintiff himself inserted the matter in the bottle in the few minutes between the purchase and the discovery. The substance was such that it would not of itself fall into the bottle, as might be the case if the matter were a bug.

As I see it, the one possibility for the bottler winning here is on the ground that he did not have control. The facts indicate that the station operator purchased the drinks. If, as appears, the cases were stored in the station for a time prior to being placed in the machine, the court might require a showing that, in fact, the bottle had not been tampered with or perhaps that there was no reasonable probability that it had been tampered with.[2]

INJUNCTION FILED TO HALT DISTRIBUTION OF COLOR-PROJECTOR DEVICE

Attorney General William P. Rogers announced, according to a Department of Justice release, that an injunction suit was filed on November 27 in the federal court at Camden, New Jersey, to halt interstate distribution of a color-projector device, together with literature representing it as a treatment for the ills of mankind. At the same time, a temporary restraining order was sought to stop promotion activities of an "institute" offering the device and of its president. The president of the institute was convicted in 1947 for nationwide promotion of a similar machine, which was offered for treating all kinds of ailments by means of colored lights. Fines totaling $20,000 were imposed, and the individual was given a three-year suspended sentence and placed on probation for five years. Investigations by inspectors of the Food and Drug Administration show that the promoter made plans to resume his activities immediately on termination of his probationary period.

According to the complaint for injunction, the promotion and distribution of the devices is carried on through the medium of the institute. Groups which include only members of the institute meet monthly in several cities of the United States; the groups are called "studios" (formerly "planets"). There are different types of affiliation.

The devices in question are used by shining lights on the parts of the bodies to be treated, following elaborate directions given in accompanying literature.—Reported in CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7420 (December 20, 1957).

[2] See *Royal Crown Bottling Company v. Smith*, CCH Food Drug Cosmetic Law Reports ¶ 22,490, 303 S. W. (2d) 270 (Ky. Ct. App., 1957).

The Scientists' Forum

By BERNARD L. OSER

Director, Food and Drug Research Laboratories, Inc.

The following paper is contributed by Dr. John P. Frawley, who currently holds the position of toxicologist with Hercules Powder Company. Dr. Frawley is also secretary of the toxicology subcommittee of the National Agricultural Chemicals Association. Prior to joining Hercules Powder Company, he was assistant chief of the Chronic Toxicity Branch, United States Food and Drug Administration, devoting much of his efforts to the study of organic phosphate toxicity and potentiation

Significance of Potentiation to Safety of Food Additives

The *Federal Register* of October 23, 1956, contained a statement of general policy issued by the Commissioner of the Food and Drug Administration regarding "test required to establish safety of organic phosphate pesticides." In effect this announcement stated that:

> . . . in considering a petition for a tolerance or tolerances for an organic phosphate pesticide, the Food and Drug Administration will require experimental evidence showing the toxicity of the compound when fed to test animals with each of the other organic phosphate pesticides that has a tolerance at that time.

The policy statement went on to say that "this requirement will be relaxed if additional scientific evidence shows such action can be taken without hazard to the public health." The scientific background for this announcement was the report [1] by a team of Food and Drug Administration scientists that up to a 50-fold potentiation in acute toxicity and from 10- to 15-fold potentiation in subacute toxicity had been observed with the simultaneous oral administration of EPN and malathion to dogs. Potentiation of a lower order with the simultaneous administration of these compounds to rats also had been observed.

Following this announcement there has been considerable effort by government, university and industrial laboratories to evaluate the

[1] J. P. Frawley, E. C. Hagan, O. G. Fitzhugh, H. N. Fuyat and W. T. Jones, "Marked Potentiation in Mammalian Toxicity from the Simultaneous Administration of Two Anti-Cholinesterase Compounds," paper presented at fall meeting of American Society for Pharmacology and Experimental Therapeutics, November 9, 1956; J. P. Frawley, H. N. Fuyat, E. C. Hagan, J. R. Blake and O. G. Fitzhugh, "Marked Potentiation in Mammalian Toxicity from Simultaneous Administration of Two Anti-Cholinesterase Compounds," *Journal of Pharmacology and Experimental Therapeutics* (1957).

magnitude of the phosphate potentiation problem, to investigate the biological mechanisms involved and to develop techniques for predicting potentiation. A committee has been formed under the National Agricultural Chemicals Association to assist in the exchange of information and the correlation of data. It is hoped that through these combined integrated efforts it will be determined whether potentiation is of any significance to the public health at spray-residue levels. Considerable progress has been made toward answering this question, but any discussion of these results now would be premature.

In addition to these experimental activities, there has been much discussion and some apprehension, at the administrative level, regarding the implication of potentiation on the protection of the public health beyond the insecticide field and in the entire field of chemical food additives. It seems appropriate, therefore, to re-examine, in light of potentiation, our present toxicological approach to the establishment of safety of chemical additives and determine whether this approach affords protection of the public health beyond any reasonable doubt. This communication attempts to present such an evaluation.

In the simplest of terms, potentiation is the phenomenon of observing that $2 + 1 = 3 + X$. More definitively, it is the phenomenon of observing that the combined simultaneous action of two compounds is greater than the expected additive action predicted from the individual action of the two compounds. It is an occurrence unique to the biological sciences and, when observed, serves as sobering testimony of our incomplete understanding of biological systems and our inability to predict with infallibility the action of compounds.

With the biologist, potentiation stirs no great emotion, for it is a phenomenon which he has heard about or observed many times. Even the layman recognizes the "Mickey Finn" as a trite example of the combined action of two depressants, ethyl alcohol and chloral hydrate, achieving a state of greater social embarrassment than should result from either alone at twice the dosage. In chemotherapy, the potentiating action of drugs frequently is used to produce greater therapeutic value. In bacteriology and pharmacology, potentiation is used as an experimental tool for screening drug combinations for greater physiological effect.

In toxicology, potentiation is equally familiar, since the deleterious effects of proposed drug combinations are carefully investigated and

weighed against the increased therapeutic effectiveness. However, possible potentiation in the toxicity of chemical additives to food, although no more unexpected scientifically, is far more complicating in method of investigation and interpretation of significance than it is for drugs. These complications are inherent in the purpose and distribution of chemical additives. Unlike drugs, which are selected on the basis of their physiological properties and are intended to produce a controlled effect in the consumer, food additives are selected on the basis of chemical, physical, pesticidal, organoleptic, or other property, and are considered safe only if it can be demonstrated that they produce *no* systemic physiological effect in the consumer. Likewise, for drugs, the selection of combinations is intentional, the number of combinations is limited by the number that produce the desired physiological effect, and the phenomenon of potentiation from these combinations is detected in the course of development. For food additives, the combinations can result from independent actions on the parts of food grower, shipper, processor and housewife; the number of combinations is limited only by the number of theoretical combinations. Since the combinations are unintentional, the possibility of potentiation usually is not investigated.

It is easy to visualize the magnitude of the potentiation problem for chemical additives if we consider the number of sources from which chemicals can appear in food. The use of pesticides; fungicides; weed killers in agriculture; intentional additives, such as preservatives, antioxidants, sequestrants, surfactants, stabilizers, colors, flavors, etc., in processing; and incidental additives from food packaging can give rise to many combinations in the same food item. The possibility of combinations is further multiplied by the number of different food items ingested at the same meal by the consumer. In 1950, it was reported [2] that the Food and Drug Administration had estimated that it was aware of the use of 704 chemicals in food. Although it is likely that many of these are used in such minute amounts and in such infrequently ingested foods that negligible quantities are involved, the figure provides a convenient working basis for estimating the theoretical experimental task of studying potentiation. The number of theoretical combinations of two compounds alone would be approximately 250,000. To investigate the acute oral toxicity of these in rats would cost in

[2] Select committee of the House of Representatives, in Rept. 2356, 82d Cong., 2d Sess.

excess of $50 million; to conduct modest chronic studies, in excess of $5 billion. Even more pertinent than the finances is the realization that such studies would saturate the entire toxicological laboratory facilities of this country for over 500 years.

These figures reveal the almost hopeless experimental task of investigating potentiation of chemical additives to food. On the surface, they may seem to suggest that protection of the public health also has reached a hopeless state. The latter is not consistent with the facts. It is important to realize that protection of the public health does not require experimental evidence of potentiating combinations any more than it requires an LD_{50} on the human species. Public health can be and is protected effectively by the use of a suitable margin of safety which, in effect, assumes that all combinations are potentiating and that the human is more sensitive than the rat and dog.

This is the practice that has been employed by the Food and Drug Administration and industrial toxicologists for a number of years. Lehman and Fitzhugh [3] have described the rationale of the "100-fold margin of safety." The application of this practice assures "that the chemical additive should not occur in the total human diet in a quantity greater than 1/100 of the amount that is a maximum safe dosage in long-term animal experiments." Superimposed on this "100-fold margin of safety" is a sizable, although indeterminable, margin of safety represented by the fraction of the individual food items that contain each additive. Thus, even if all additives appeared in 20 per cent of the food, the use of these margins of safety would protect against simultaneous 50-fold potentiation and 10-fold increase in human susceptibility for all combinations.

However, as Lehman and Fitzhugh [4] have stated: "The '100-fold margin of safety' is a good target but not an absolute yardstick as a measure of safety." Some chemical additives have a smaller margin of safety. The justification lies in the very purpose of the margin of safety. This fundamental purpose is to protect the consumer against any toxic effects that could not be detected experimentally. It is a substitute for knowledge, assuring that any error be in favor of the consumer. Consequently, the size of the margin of safety is inversely proportional to the amount of information available on the action of the compound. For example, if the chronic toxicity has been investi-

[3] A. J. Lehman and O. G. Fitzhugh, "100-Fold Margin of Safety," 18 *Quarterly Bulletin of the Association of Food and Drug Officials* 33 (1954).

[4] See footnote 3.

gated thoroughly in two or more species of animals, if a sensitive tool is available for detecting the physiological actions, if the metabolic fate is well determined and if the relative sensitivity of the human species is known, the margin of safety can be small. Likewise, the margin must be correspondingly larger with the absence of information on one or more of these factors.

With most chemical additives, the margin of safety is high, adequate to protect against potentiation of a high order. The margin of safety for some organic-phosphate insecticides, however, has been smaller.[5] As a group of compounds, probably more is known about the physiological action and toxicity of phosphates than of any other group. It has been demonstrated repeatedly that no pathological changes are associated with the chronic administration to animals; knowledge of the physiological action has led to the development of a sensitive tool for detecting cumulative physiological changes; and limited human studies have suggested the relative sensitivity of man as compared to laboratory species. Thus, a safe level for these compounds could be predicted more reliably and a smaller margin of safety could be employed between the safe level for experimental animals and the permissible residue level for human food. However, with evidence of potentiation with two of these compounds, the justification for the smaller margin of safety was at stake. Therefore, it seems that the Food and Drug Administration had no choice but to insist upon a re-evaluation of the organic-phosphate pesticide picture in the light of potentiation.

It is significant to note in this announcement that the requirement for all phosphate pesticides to be tested experimentally for potentiation properties "will be relaxed if additional scientific evidence shows such action can be taken without hazard to the public health." Much experimental information has been accumulated since the issuance of this order. It has shown that potentiation with phosphate pesticides is the exception rather than the rule.[6] Additional work by Food and Drug Administration scientists [7] and industrial toxicologists is uncover-

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[5] J. P. Frawley, H. N. Fuyat, E. C. Hagan, J. R. Blake and O. G. Fitzhugh, work cited at footnote 1: J. P. Frawley and H. N. Fuyat, "Effect of Low Dietary Levels of Parathion and Systox on Blood Cholinesterase Activity of Dogs," 5 *Journal of Agricultural and Food Chemistry* 346 (1957).

[6] M. W. Williams, H. N. Fuyat and J. P. Frawley, "Blood Cholinesterase Studies with Simultaneous Administration of Several Combinations of Two Organic Phosphate Insecticides," 16 *Fed. Proc.* 347 (1957).

[7] J. W. Cook, J. R. Blake and M. W. Williams, "The Enzymatic Hydrolysis of Malathion and Its Inhibition by EPN and Other Organic Phosphorus Compounds," 40 *Journal of the Association of Official Agricultural Chemists* 664 (1957).

CANADA-

FOOD AND DRUG ITEMS

An interesting note has been submitted to the JOURNAL by F. S. Thatcher, head of the microbiology section of Canada's Food and Drug Directorate. In a covering letter, Dr. Thatcher wrote:

"The accompanying note is offered for your consideration as a response to a question reported in the August edition of the FOOD DRUG COSMETIC LAW JOURNAL, and directed by Dr. M. Ingram to Drs. C. A. Morrell and F. S. Thatcher, authors of the paper "Antibiotics in Foods"; and presented to the Joint-Meeting in London recently."

Dr. Thatcher's note follows:

"Antibiotics as Food Additives

"At the recent conference on Chemical Additives in Foods held at the Royal Institution, London, a question was directed by Dr. M. Ingram to Drs. C. A. Morrell and F. S. Thatcher, the authors of the paper 'Antibiotics in Foods' (and of this present note). The authors were unable to attend the conference, but express their thanks to Mr. Charles Adams who accepted the unenviable task of reading their paper for them.

"Dr. Ingram's question concerned criteria listed for acceptance of an antibiotic as a food preservative, and specifically, 'The fifth of these criteria, if I have it rightly, was that the antibiotic should induce no abnormal spoilage pattern.' Dr. Ingram continued to illustrate that any effective amount of antibiotic must inevitably modify the spoilage flora in treated foods. This had been shown by the development of numerically dominant populations of yeasts in foods treated with tetracyclines.

"The statement referred to by Dr. Ingram occurred in a list of conclusions and was expressed as follows: 'Any permitted use in or on foods should be subject to repeal in the event that (a) their microbial selectivity gives rise to new or "abnormal" forms of spoilage or disease or (b) evidence for the significant increase in the prevalence of antibiotic-resistant pathogens as a result of their use in foods becomes apparent.'

"The general observation is made in the text of the paper, '. . . whenever the normal micro-ecology of a mixed population is disturbed by any selective process, the risk arises that specific populations or species normally held in check by competitive microbial action may become dominant and, on occasion, may give rise to new forms of spoilage not normally encountered'. A number of illustrations were then given, including reference to those 'where antibiotics are the equilibrium-disturbing factor', and with appreciation of the potential effects of both 'natural' selectivity and that resulting from induced resistance to a given antibiotic. We would expect that when an antibiotic-treated food does eventually spoil, its component flora would differ from its untreated counterpart.

"Thus, the response to Dr. Ingram's question would have been agreement

with the principle that he expressed, and by way of further clarification of the statement in question we would add that another way of expressing its intent would be: (1) There will be no value in the use of antibiotics if one spoilage pattern is simply replaced by another during the expected shelf-life of the treated food; (2) if pathogenic organisms multiply more rapidly in the absence of some of the usual flora and their numbers increase to significant levels; or if antibiotic-resistant pathogens occur with significantly greater frequency as a result of treatment then we would have every reason to become concerned.

"Present evidence fails to establish a health hazard, and the shelf-life of poultry and fish continues to be extended by treatment with the permitted antibiotics. However, Canada has the necessary legalistic machinery for prompt amendment of the pertinent Regulation under the Food and Drugs Act if positive evidence should point to the likelihood that significant hazards may materialize.

"As we also pointed out in our paper, 'final conclusions on specific aspects . . . can only be determined after appropriate experience'. Until such time, some measure of subjective decision cannot be avoided."

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ing simplified techniques for screening for potentiating combinations. The future course for experimental design and the use of a small margin of safety for phosphate pesticides are vitally dependent on the facts being developed during this period of re-evaluation.

Thus, the problem of potentiation is of possible significance to the protection of the public health only for those few food additives that are used with a small margin of safety. The phosphate pesticides are representative of this category; current investigations will reveal whether potentiation with these compounds is of any real significance to the public health. It is a certainty that the current and future work will uncover fundamental information on the action of these compounds and will lead to more intelligent estimates of a safe level with or without potentiation.

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